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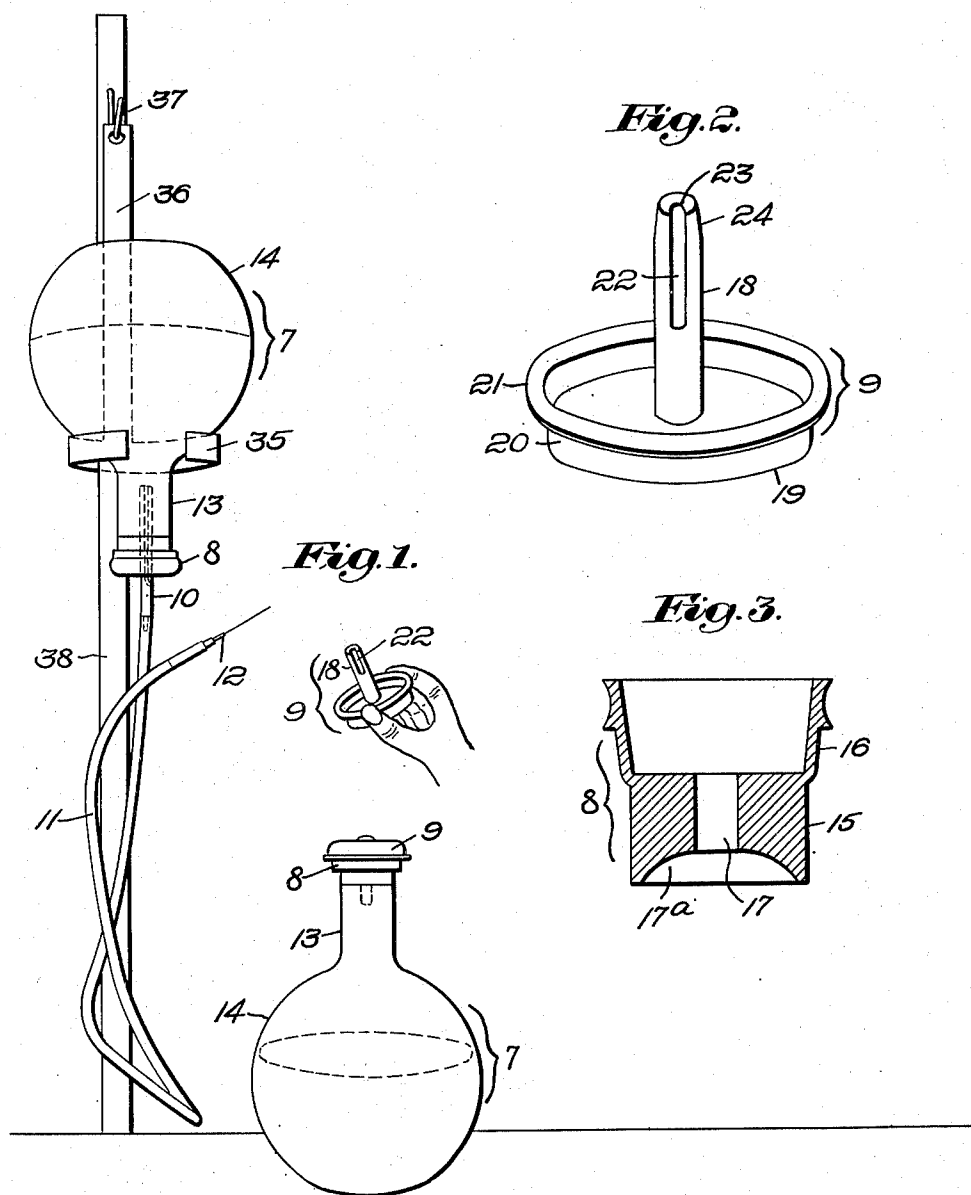
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2,116,132

APPARATUS FOR AND METHOD OF PREPARING, STORING, AND DISPENSING FLUIDS

Filed March 4, 1936

2 Sheets-Sheet 1



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2 Sheets-Sheet 2

Fig. 6.

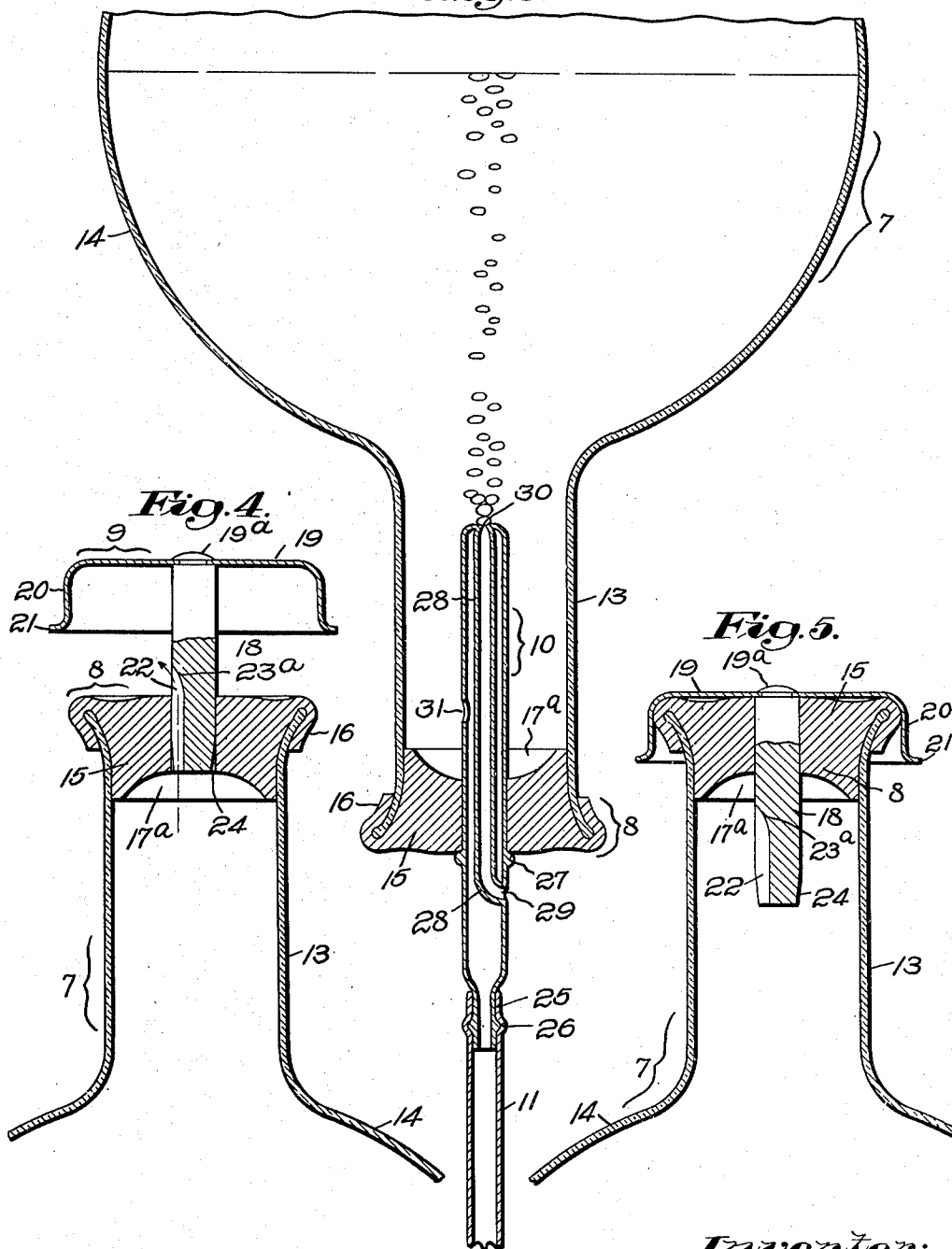


Fig. 5.

Fig. 4.

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UNITED STATES PATENT OFFICE

2,116,132

APPARATUS FOR AND METHOD OF PREPARING, STORING, AND DISPENSING FLUIDS

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16 Claims. (Cl. 128—214)

My present invention relates to apparatus for and methods of preparing, storing and utilizing fluids, more particularly in uses where an uncontaminated or sterile condition of the fluid is important, as in the medical and surgical fields. While susceptible of more general use, the apparatus and method of the invention are especially adapted for the preparation, storage and administration of parenteral fluids.

In the drawings, illustrating by way of example one apparatus embodying the invention, and by means of which the method thereof may be practised,

Fig. 1 shows the apparatus as a whole;

Fig. 2 is a perspective of one element of the closure means, namely the stopper, upon a larger scale;

Fig. 3 is a cross-section of a flexible, resilient bushing used in the apparatus;

Figs. 4 and 5 are sectional views, on substantially full scale, showing a portion of the apparatus in the preparation and storage conditions respectively; and

Fig. 6 is a sectional view on a similar scale as Figs. 4 and 5 showing a portion of the apparatus in use, as in Fig. 1.

The production of a reliable supply of various fluids, including particularly parenteral fluids, in their localities of use, such as otherwise adequately equipped hospitals, has heretofore been hindered by the lack of simple methods and apparatus by means of which chemically pure solutions and fluids can be prepared, stored and dispensed safely and economically. In accordance with the means and methods of my present invention, this difficulty is obviated.

Referring more particularly to the drawings, and first to Fig. 1, the apparatus as a whole, as there illustrated by way of example, includes any required number of vessels or flasks 7 for the reception of the parenteral or other fluid, and, for each flask, a tight fitting bushing 8, a stopper or stopper element 9, a vent-tube or outlet element 10, a flexible conduit 11 and the parenteral introductory means or needle 12.

The flask 7 is preferably formed of a heat-resistant glass such as employed for chemical and surgical purposes, for example as known under the trade-mark "Pyrex". Desirably it has a relatively short neck 13, as compared with usual articles of this type, and the body portion 14 is thickened or reinforced to withstand internal negative pressures or partial vacuum. The neck and mouth and particularly the lip around the latter desirably also are of a thickened or heavier

structure, for cooperation with the stoppering means.

The parenteral or other fluid to be sterilized and stored for use is placed in the flask 7 and the special bushing 8 is inserted in the flask mouth. As best seen in Fig. 3, showing such bushing before application, the latter includes a reducing or plug portion 15 and a skirt 16 adapted to be turned down externally about the mouth of the flask. The bushing is formed of rubber, rubber composition or other non-toxic and heat-resistant resilient material adapted to retain its resiliency after repeated subjections to heat and to have hermetic sealing engagement with the flask. As shown, the bushing is provided with a single central through aperture 17 for the alternate reception, at different stages of the process as a whole, of the stem 18 of the stopper 9, and of the dispensing valve or vent-tube 10. The diameter of this single aperture, and hence of the stopper stem 18 and the vent-tube 10 is desirably not greater than the thickness of the wall of the plug portion of the bushing. The inner or bottom face of the bushing may be variously formed, either dished as indicated at 17^a or otherwise. The bushing and stopper proper 9, in combination constitute stoppering means for the flask, and the bushing in conjunction with the vent-tube 10 cooperates as releasing or dispensing means.

The stopper 9 in accordance with the invention is composed of a material which not only is non-corrosive and chemically resistant but also is capable of effective sealing but non-sticking engagement with the bushing. Accordingly, as a result of extensive experiment, I employ in the preferred embodiment a stainless steel, for example, Carpenter Group 4 stainless steel, which actual practice has proven to be highly satisfactory for the purpose. Within the contemplation of the invention, however, other metallic or non-metallic materials may be used provided they possess the desired properties of non-corrosiveness, lack of harmful reaction with the rubber or composition of the bushing, non-adhesiveness therewith to any objectionable extent, even at sterilizing temperatures, and have a surface texture or consistency cooperative with the rubber or rubber composition of the bushing to effect a gas-tight seal.

The stopper 9 comprises the central stem 18 referred to and a cap member 19 integral or rigidly connected to and sealed with respect to the stem, as by firmly riveting, welding or otherwise, as seen at 19^a. The cap member includes a sub-

stantially flat base or cover portion of an area corresponding to that of the bushing 8 when positioned with its skirt down-turned as in Figs. 4, 5 and 6, and a peripheral flange 20 with out-turned lip 21 substantially as illustrated, the flange being receivable over the down-turned skirt of the bushing and extending substantially downwardly over it. The neck of the flask, the bushing and the stopper are proportioned and arranged to fit snugly with respect to each other, as illustrated in Fig. 5, and in such manner as to form an hermetic seal under the conditions to be described, which sealing action is increased in the presence of negative pressure within the flask.

The stem 18 of the stopper is provided with a longitudinal vent or channel 22 for the constricted escape of air, steam or other gas when the stopper is in partly inserted position, as in Fig. 4. This vent may be variously formed, but for the purposes of simplicity and cleanliness is fashioned as an open channel or groove of relatively small cross-sectional area, as compared with that of the stem as a whole. Preferably it has a rounded bottom as indicated at 23, see Fig. 2, and sloping outwardly at its end nearer the cap, as at 23', Figs. 4 and 5, to avoid corners or angles in which dirt might collect, and to make it easier to clean. This channel 22 is formed in the lower portion of the stopper stem and is of a length desirably at least equal to the vertical central thickness of the plug portion 15 of the bushing 8 so that the channel may provide a passage completely through the central aperture 17 of the bushing when so desired, as during sterilization of the fluid.

The stem has a total length, including the solid unchanneled portion between the channel 22 and the cap, of sufficient extent so that when the stopper is completely inserted, as in Fig. 5, the channel comes largely or wholly beyond the inner end of the bushing and the aperture in the latter is effectively closed by the solid part of the stem. Accordingly, as will be noted from a comparison of Figs. 4 and 5, the over-all length of the stem desirably is at least approximately twice the vertical length or thickness of the central part of the plug portion of the bushing. Obviously it is not essential that the channel 22 be carried to the extreme end of the stem if the latter is given a length in excess of that necessary to the functions described, so long as the stem and channel are so proportioned and arranged with respect to the bushing as to provide for their venting and their sealing positions with respect to each other.

The stopper stem and its channel desirably also are formed and proportioned for the purpose of affording an audible signal attendant on the passage of air, steam or other gases through the channel, in either direction, useful in a manner more fully referred to later. This audible sound or signal is in the nature of a whistling action, dependent in part on the small cross-sectional size of the channel, having reference to the gas pressure likely to be available, and in some part on the conformation of the channel whereby the controlled passage of the air or other gas effects the desired whistling or signaling action. The free end of the stopper stem may be rounded off or tapered, as indicated at 24, to facilitate its insertion in the bushing.

In the preparation of one form of parenteral fluid, fresh singly distilled water is drawn from the available supply, preferably prepared especially for the purpose. Isotonic sodium chloride solution, preferably of the strength 0.85%, is

prepared from a fresh stock solution as by adding 170 grams of C. P. sodium chloride previously weighed out in a counter-balanced flask, up to a net weight of 1108 grams. This solution is then filtered, with the aid of suction, directly into a 300 c. c. "Pyrex" burette equipped with a clean rubber stopper. After the solution is complete, fifty cubic centimeters of this filtrate may then be measured into a counter-balanced 1500 c. c. flask, such as the flask 7 here illustrated, distilled water being added to a net weight of 1049 grams. A clean bushing 8 is then fitted into the mouth of the flask, the skirt 16 of the bushing is turned down, and the stem 18 of the stopper 9 is partially inserted, as shown in Fig. 4.

Each such flask with its partly inserted stopper is then subjected to heat treatment in any convenient manner, preferably in an autoclave or sterilizer, the recommended temperature and time being 250° F. for 20 minutes. During the sterilizing operation, the air, steam or other gases from within the flask pass off through the channel 22 in the stopper stem. Following such period the steam supply to the autoclave is shut off and the latter is permitted to cool to 180° F. before being opened. This avoids undesired concentration of the solution resulting from the ebullition of steam which would follow a sudden release of pressure. But if for any reason the sterilizer is prematurely opened and a resultant concentrating effect upon the solution occurs, the steam or gas passing out through the stoppering means, then still elevated, produces the audible signal or whistle previously referred to, and hence automatically informs and warns that the solution has been spoiled for the intended use, in such cases where excess concentration is dangerous or undesirable.

Where cooling within the sterilizer has been properly effected, absence of an audible signaling effect at the stoppers of the flasks gives assurance that the concentration of the fluid has not been unduly increased, and the flasks are ready for removal. Attendant on removal of each flask from the autoclave or sterilizer, its stopper 9 is immediately pushed or driven home into the completely hermetic sealing position as illustrated in Fig. 5. The nurse or operator may conveniently do this with the palm of the hand applied only to the top of the stopper cap 19, so that no portion of the apparatus which is to be contacted by the fluid will be exposed or touched. The hermetic seal is effected by the close, pressure fit between the stopper and the down-turned skirt of the bushing and between the latter and the neck of the flask. This sealing action is augmented and insured by the further cooling of the contents of the flask, resulting in an internal negative pressure which effects an absolute sealing engagement between the parts referred to. Pressure on the base of the bushing, whether the latter be concave or otherwise, tends to spread the lower, plug portion of the bushing, forcing it into intimate contact with the wall of the flask neck.

This formation of a partial vacuum within the flask in the manner described is utilized for the additional important function, at the time when the contents of the flask are to be used, of informing that such contents have remained in the desired sterile condition. This is because subsequent withdrawal of the stopper, when the flask and its contents are to be utilized, produces a similar audible signal as already referred to in connection with insufficient cooling, in this instance caused by the inrush of air to replace the

partial vacuum. If the nurse or operator fails to receive the sound signal when the stopper is released, it is then apparent that the fluid contents have not been properly sterilized or have been tampered with.

The vacuum or partial vacuum formed in the sealed flask as it cools, in the manner previously described, also serves the additional function of enabling a nurse or other person who has occasion to examine the flask to determine immediately and without breaking the stoppering seal that the hermetic seal has been maintained and that accordingly the fluid contents retain their sterile condition. The vacuum within the sealed flask normally is such as to afford a water hammer effect, so that by merely tilting or jarring the flask sufficiently to move the fluid contents a distinct ringing, knocking or hammering sound is produced, due to the contact of the fluid contents with the flask wall in the presence of the negative pressure within the flask. Failure to note this sound effect when the fluid contents are disturbed may be considered as an indication that the sealing of the flask has been tampered with or has failed for some reason and that the contents accordingly are unsafe.

Any required number of flasks containing solutions prepared and sterilized as described can be stored indefinitely without impairing the contents of the flasks as safe parenteral fluids. The stoppering means described affords an efficient and sterile seal, preserving the sterile condition of the fluid indefinitely and in the original container, so that it is instantly available for use by the clinician whenever desired.

When the fluid is to be administered it is but necessary to withdraw the stopper 9, checking the condition of the contents by means of the occurrence or non-occurrence of the audible signal. Sounding of the signal at this time, it will be understood, is indicative of correct conditions, whereas its occurrence at the earlier stage of the process as previously described signifies non-correct conditions. That is, at the cooling step it is a stop-warning, while at the fluid-administering stage it is a confirmatory signal. A sterile vent-tube 10 is at once readily inserted in the bushing, the tube having removably attached to it a sterile flexible conduit or rubber hose 11 and the needle 12. A sufficient supply of sterile sets of such vent-tubes, rubber tubing and needles preferably is kept at hand, one for each flask to be utilized.

As best seen in Fig. 6, the dispensing valve or vent-tube 10 comprises an elongated tubular member having a main external diameter corresponding to that of the stem 18 of the stopper 9, and of the aperture 17 of the bushing, so as to form a tight fit within the latter. This vent-tube may be composed of any suitable material capable of heat sterilization, but preferably is made of a strong and heat-resistant glass, such as commercially known under the trade-mark "Pyrex". One end of the tube has a reduced portion or nipple 25 for the reception of the rubber tubing 11, a bead 26 desirably being formed on the nipple to aid in retaining the tubing in place. The tube is of a length adequate to extend through the bushing and for some distance into the flask. The extent of entrance of the tube may be directed and limited as by means of a stop such as the external rib or bead 27.

To provide for free gravity flow of the fluid from the flask the latter is inverted, and valve means is incorporated in the vent-tube 10 so

to permit the entrance of air sufficiently to counteract negative pressure within the flask. Accordingly, as illustrated, the tube 10 is formed with a longitudinal air-inlet passage or duct 28 having an inlet aperture 29 externally of the positioning bead 27 and terminating at or near the end of the tube opposite the nipple 25 in a small capillary orifice 30. The size of this orifice is such that the surface tension of the liquid thereat is adequate to support the weight of the maximum column of liquid within the flask above the orifice.

Outlet for the liquid contents of the flask is provided by means of the larger orifice 31 located at any convenient position in the main wall of the tube, and sufficiently spaced from the positioning bead 27 so that said orifice comes within the flask and clear of the bushing 8 when the vent tube is inserted, as in Figs. 1 and 6.

In administering the fluid in accordance with the method and apparatus of my invention, a sealed flask with sterile contents, such as shown at the lower right portion of Fig. 1, and in Fig. 5, has its stopper removed, as in the manner indicated in Fig. 1. A sterile vent-tube 10, with clean tubing 11 and needle 12 attached, is immediately inserted in the single aperture in the bushing, wherein it has a sealing fit due to the described proportioning and construction of the apparatus as a whole. It will be noted that during such operation no surface to be contacted by the fluid need be engaged by the hand of the operator or attendant. Only the peripheral flange of the stopper need be engaged, while the inner end of the vent-tube engages only sterile portions of the bushing. The flask with inserted vent-tube is then inverted and supported in any suitable manner to afford a gravity flow. For this purpose I have found it convenient to use supporting means as shown in Fig. 1, including a split collar or ring 35 attached to a hanger 36 adapted to be hung on a hook or the like 37 on a transportable standard or other support 38.

From the foregoing it will be apparent that by use of the method and apparatus of my invention hospitals, clinics and the like are enabled to prepare parenteral and other fluids and solutions, to store the same conveniently and in adequate quantity, and to administer the same from the original container, with all reasonable assurance of safety.

It will be understood that my invention, either as to means or as to method, is not limited to the exemplary embodiments or steps herein illustrated or described, its scope being set forth in the following claims:

I claim:

1. An improvement in preparing, storing and utilizing parenteral and other fluids, which comprises, in combination; a heat-resistant flask adapted to sustain an internal partial vacuum; a one-piece resilient non-toxic and heat-resistant bushing for the mouth of the flask, said bushing having a single cylindrical through aperture of substantially uniform diameter; a non-corrosive metal stopper cooperable with the bushing to afford an hermetic seal for the flask, said stopper comprising a flanged cap adapted to seat on and enclose the upper portion of the bushing and the flask mouth and a cylindrical stem having a sealing fit in the bushing aperture and provided with a restricted passage for gas in a portion of the stem spaced from the cap; and a readily sterilizable transparent, one-piece venting member of substantially cylindrical external form adapt-

ing it for non-contaminating reception in said aperture of the bushing, said venting member having a capillary-valved longitudinally extending air inlet passage and a separated fluid outlet passage terminating in a portion adapted for the connection thereto of a flexible conduit.

2. Fluid-handling apparatus comprising, in combination; a heat-resistant container having a restricted mouth; a bushing fitting the container mouth and having a single through aperture; a stopper element adapted to close said bushing aperture and having a restricted gas channel arranged to provide passage for gas in the partly inserted position of said element and to be completely blocked in the fully inserted position thereof; and a dispensing tube also receivable in said bushing aperture interchangeably with said stopper element and adapted to extend through the bushing sufficiently to afford a controlled exit for the fluid from the container, said tube having integrally incorporated internally thereof a capillary-valved passage for vacuum-relieving ingress of air and being formed at its outer end for the attachment of a flexible conduit.

3. Fluid-handling apparatus comprising, in combination; a heat-resistant container having a restricted mouth; a bushing fitting the container mouth and having a single through aperture, said bushing consisting in a one-piece element comprising a relatively thick-walled reducing or plug portion through which said aperture extends centrally, the latter having a diameter not substantially exceeding the wall thickness of said plug portion, and a peripheral skirt above and adapted to be turned down so as to tightly enclose the flask mouth and upper end of the said plug portion, said bushing and flask mouth being mutually shaped and constructed to resist undue inward movement of the positioned bushing in the presence of a negative pressure within the flask, and said bushing being integrally formed of a flexible, resilient material which retains its resiliency and otherwise withstands repeated subjection to heat and moisture at sterilizing temperatures; a stopper element adapted to close said bushing aperture and having a restricted gas channel arranged to provide passage for gas in the partly inserted position of said element and to be completely blocked in the fully inserted position thereof; and a dispensing tube also receivable in said bushing aperture and adapted to extend through the bushing sufficiently to afford a controlled exit for the fluid from the container, said tube having integrally incorporated therewith a capillary-valved passage for vacuum-relieving ingress of air and being formed at its outer end for the attachment of a flexible conduit.

4. Fluid-handling apparatus comprising, in combination; a heat-resistant container having a restricted mouth; a bushing of rubber composition fitting the container mouth and having a single through aperture; a stopper element adapted to close said bushing aperture, said stopper element being composed entirely of stainless steel of a surface texture adapted to have sealing but non-adherent engagement with the rubber composition of said bushing and comprising a substantially flat cap having a down-turned peripheral flange and an elongated depending central stem of relatively small diameter as compared with the cap and conforming to the bushing aperture, said stem having in a portion thereof of spaced from the cap a longitudinal gas chan-

nel of restricted cross-sectional area, the spacing of the channel from the cap being sufficient to provide for blocking the channel when the stopper cap is inserted flush with said bushing; and a dispensing tube also receivable in said bushing aperture and adapted to extend through the bushing sufficiently to afford a controlled exit for the fluid from the container, said tube having integrally incorporated therewith a capillary-valved passage for vacuum-relieving ingress of air and being formed at its outer end for the attachment of a flexible conduit.

5. Fluid-handling apparatus in accordance with claim 4 wherein the longitudinal gas channel in the stopper stem has a length, conformation and cross-sectional area whereby in the use of the stopper the passage of gas under pressure through the channel in either direction is designed to produce a distinctive audible signal.

6. The method of preparing, storing and utilizing parenteral fluids which comprises stoppering the fluid in a container in a manner affording a restricted gas exit and sterilizing the fluid in the container while so permitting the escape of gas, sealing the container after sterilizing by completing the stoppering thereof so as to close the gas passage, substituting in the stoppering means a dispensing unit receivable interchangeably in the place of the sealing means, and affording egress to the fluid through said dispensing unit while avoiding negative pressure within the container, thereby utilizing the original container to insure and maintain the sterile condition of its fluid content continuously from preparation through and including storage and use.

7. In fluid-handling apparatus, in combination, an apertured bushing for the mouth of a fluid container, said bushing having inner and outer ends, a tubular member received in and extending through the aperture of the bushing and projecting beyond the respective ends thereof to provide a passage for the fluid, including an outlet beyond the outer end of the bushing and an inlet beyond the inner end of the latter but substantially spaced from the inner projecting end of the tubular member, projecting means on the outer wall of the tubular member and engageable with the bushing for positioning it relatively to the latter, and a longitudinal channel formation carried by the tubular member intermediate its ends and so positioned and of such length as to extend in the opposite directions beyond the bushing-engaged portion of the tube and at one end opening to atmosphere outwardly of said positioning means and adjacent the outer end of the bushing, and at its other end provided with a capillary valving formation for the passage of air and exclusion of the fluid by means of surface tension thereat.

8. A combined unitary fluid-dispensing and vacuum-relieving device for fluid-handling apparatus, comprising a main tubular member of heat-resistant glass, said member having outer, intermediate and inner portions, said intermediate portion adapted for holding reception in a bushing for the mouth of a fluid container, said outer portion having an exit for discharging fluid and said inner portion having a closed inner end and having a fluid admitting aperture spaced from said closed end and communicating through the intermediate portion with said fluid exit, and integral channel means extending from a location outwardly of the intermediate portion to a location inwardly thereof and terminating at said latter location in a capillary-valve-forming pas-

sage for the controlled ingress of air during outflow of a fluid through said main tubular member.

9. A fluid dispensing element for fluid-handling apparatus comprising a fluid outlet tube having an inner end closed to the fluid, an intermediate inlet for the fluid and an outlet for the latter at its outer end portion, said tube having integrally associated with a wall thereof a longitudinal air channel provided at its end nearer the fluid inlet with a capillary-valve-forming passage for air to the exclusion of the fluid.

10. A fluid dispensing element for fluid-handling apparatus comprising a fluid outlet tube including a container-entering portion having integrally incorporated with it a passage for communicating between the inside and outside of a container, said passage formed at its inner portion with a capillary air-inlet valving aperture proportioned and arranged to support by surface tension a calculated fluid column above it.

11. A fluid dispensing element in accordance with claim 10, wherein said element in its entirety is of one-piece heat-resistant glass construction.

12. A fluid dispensing element in accordance with claim 10, wherein the outlet tube embodies a chamber for a fluid column adequate to create a negative pressure to break the balance and automatically to start the outflow of fluid through the tube and ingress of air through the capillary-valved passage.

13. A dispensing vent-tube for liquid-handling containers, said tube being integrally formed of heat-resistant glass material and comprising a main tubular element having one end open and formed for the attaching reception of a flexible conduit, said element including, in order from said end, an outer portion, an intermediate portion for holding reception by the container, and an inner portion for positioning within the container and having its inner end closed to fluid, a capillary aperture in the wall of said inner portion, an aperture in the wall of said outer portion, a relatively small-diametered tube within said main tubular element and establishing closed communication between said apertures so as to

provide a capillary valve for admission of air to the container, and a liquid outlet in the wall of said inner portion and spaced from the inner end thereof for the passage of liquid through said main tubular element and outwardly through its open end.

14. A dispensing vent-tube for liquid-handling containers, said tube being integrally formed of heat-resistant glass material and comprising a main tubular element including a supporting portion and an inner or container-entering portion, the end of said element outwardly of the supporting portion being open and formed for the attaching reception of a flexible conduit, said element having in the wall of its inner portion and below the inner end thereof a fluid admitting aperture communicating with said open end, and valved air-inlet means including a capillary air-admitting valve on the container-entering portion of the tubular element, an air-admission aperture positioned between said valve and the open end of the tubular element, and a tubular passage providing closed communication between the air-admission aperture and the air-admitting valve.

15. A dispensing tube in accordance with claim 14 wherein the device as a whole is of uniform cylindrical external conformation throughout save for a reduced conduit-attaching portion at its open end and bead-like positioning means intermediate its ends.

16. An integral one-piece dispensing device formed of heat-resistant glass and adapted for reception in a bushing in the mouth of a fluid container, said device comprising a main tube having an intermediate portion for supporting reception by the bushing, a fluid-outlet formation on the tube outwardly of the bushing position, a communicating fluid-outlet aperture in the wall of the tube portion inwardly of said bushing position, a capillary air-valving formation on said last-named portion, and air passage means extending lengthwise the main tube and affording closed communication between said capillary air-valving formation and atmosphere.

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